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March 25, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 02N-0278 – Comments on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Gentlemen,

We are a small Custom Brokerage firm located at the ports of Los Angles/Long Beach and LAX. With a large client base in the seafood and produce industries I feel we have first hand actual operational knowledge with which to comment on the proposed FDA Prior Notice requirements. We support the efforts for national security and feel a workable solution to the mandated requirements of the Public Health Security and Bioterrorism Preparedness Act of 2002 can be achieved, but it must be done within a framework that does not adversely affect the consumer, our economy, or the United States position in the world marketplace. It is obvious the drafters of this NPRM did not have a complete understanding of the real world commercial practices by parties involved in the intermodal supply chain of international commerce. This also reflects the unwillingness of the FDA to tap the vast reservoir of knowledge contained in the trade community in its preparation of this proposal. Many trade organizations and individuals offered assistance in drafting a workable solution to the requirement of the Act but the agency did not accept the offers.

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Customs Brokers
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OTI #08701

We still feel a workable solution can be found, but not by the requirements of this NPRM. It is imperative the FDA work closer with other federal agencies pursuing similar security issues. The FDA must increase its efforts to utilize information now available within government databases. Duplication of information processing is inefficient use of the FDA resources and adds excessive burden to the trade community. The following comments are offered in a spirit of cooperation and serious concern on how they would impact the trade community.

Prior Notice requirements under Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Section 307 of the Act only requires seven data elements for prior notice of imported foods:

The article description
Manufacture
Shipper
Grower (if known)
Originating country
Country from which product was shipped
Anticipated port of arrival

The Prior Notice proposal as outlined in the February 3, 2002 Federal Register expands the required data elements and adds new elements far beyond the intent of Congress. No reason is provided for this additional information, at the time of Prior Notice, and far exceeds the data required by other agencies under the Department of Homeland Security for targeting selectivity of possible instruments of mass destruction and Bioterrorism. Many of the required data elements such as entry number, entry type Customs and FDA line item numbers, HTS numbers, and all other Customs information are items required for admissibility. Almost all of the seven required data elements required are contained in and provided to FDA in the Customs/OASIS interface. By requiring all Customs and FDA line item information it would require the processing of the Customs entry or "In-Bond" documentation prior to preparing and transmitting the Prior Notice. This proposal requires vast amounts of information, which is duplicated during the OASIS transmission. It would be far more efficient to require complete entry and in-bond documentation presentation within the prescribed time lines of the proposal. Any information now not included in the present OASIS transmission could be included in the affirmation of compliance sections of the FDA OASIS screen. In this way FDA would have all the necessary information for prior screening to target and isolate questionable shipments and also determine admissibility of all import shipments destined for U.S. consumption. If FDA should require additional information on a specific shipment it could require hard copy information via notification thru the Customs

ABI system. This is the system being used by Customs and USDA and has a minimum impact on the general flow of international trade while still giving a high level of confidence in the selectivity process. By having all data available at he same time it would better utilize FDA limited resources by not having to review the same data several times. For "In-Bond" shipments, where no entry will be completed, only the basic seven required elements could be filed thru a simplified reporting system.

The duplication of data and costs required by this proposal can be vastly reduced by using data now being collected by other agencies and available within established security programs. U.S. Customs is now requiring full manifest information be furnished into the Automated Manifest System 24 hours prior to loading of vessel cargo. This program will be expanded to include air and land transportation in the near future. FDA was inaccurate in the assumption that this data could not be obtained by the present interagency channels. By opening up the manifest information for direct download into the FDA OASIS system and the filing of the present entry data, within the required prior notice time limits, much of the data duplication would be eliminated. The Department of Agriculture now uses the screening of manifest data in accomplishing their security issues. This would also reduce the cost for FDA review time as all

FDA believes information available at the time article is ordered or purchased.

In the real world of international trade many of the products are purchased on a C&F or CIF bases where the actual routing and intermodal shipping process is not determined until the actual shipment is made. Some orders or purchases, as in the seafood and produce industries, are made on a blanket bases with numerous increment shipments over a period of time. With the vast of information required by this Prior Notice proposal these types of tractions would be hindered or even prohibited in the air or land border environments. These shipments are both fresh or frozen arriving on a 24 hour basis with very short transit time from Canada and Mexico. With so much of the admissibility information being required for Prior Notice many of these shipments would incur automatic refusal at arrival. This would cause a large amount of congestion and backlog at the boarder ports and as little or no refrigeration facilities are available at airlines cargo would be placed at risk. The proposal makes no provision for shipments split, during intermodal transit, by air carriers due to lack of space. Most of the information required by Congress under the Prior Notice provision is available within the present government database. U.S. Customs is now requiring 24-hour advance manifest information prior to loading of cargo. USDA also has access to the Customs manifest information. FDA should utilize this information now being furnished to

Customs as part of the Prior Notice proposal rather then requiring the international trade to furnish the same redundant information repeatedly. The repetitive split shipment where only the quantity and arrive information would change some type of blanket notification would reduce the costs to the trade and increase efficiency of FDA personnel.

FDA notes that the submitter is the entity responsible for ensuring the adequacy and accuracy of the Prior Notice.

A fast amount of the proposed information cannot be determined until the Customs entry has been prepared. In most cases a Customs Broker would be utilized to prepare both the prior notice and customs documentation. The broker is not a party to the transaction and takes information form the importer of record, shipper, and carrier as it presented to them. The broker would be the entity submitting the information but has no responsible way to verify the information being furnished is completely accurate or complete. To hold them completely responsible would be to say the messenger is responsible for the message. The proper entity for ensuring adequacy and accuracy should be the entity responsibility for presenting the merchandise for entry into or through the United States. Under U.S. Customs and even your own regulations the Importer of Record is the responsibility party. Why should that responsibility be shifted under this proposal?

Notice must be submitted by noon of calendar day before but not prior to five days of arrival.

The Act states that notice of not less than 8 hours is required. This proposal does not give adequate reasons to extend the minimum time to noon of the prior day. In the air and land boarder environment noon the prior day to arrival is not practical or reasonable. As a general comment I would suggest that FDA should work with Customs to have the AMS manifest system opened up for FDA review. A large amount of the required information is already on file with Customs. Other agencies such as U.S. Customs and Department of Agriculture PPQ use the manifest to target containers for special attention with no additional cost to the economy or restriction to international trade. This Prior Notice proposal, as presented, is penalizing all food imports, as large amounts of information is being required to isolate a small number of questionable imports. The data furnished is not being utilized to determine admissibility and thus adding inefficiency and unnecessary costs to our international trade. All other agencies responsible for security have accomplished their mandates without the costly requirements of this proposal.

Prior Notice System will only provide electronic acknowledgement of receipt

The Prior Notice proposal requires for each entity the transmission of registration numbers and re-entry of much of the registration information. The proposal suggests that an acknowledgement of receipt will be furnished but no validation of the data will be made. The information in the FDA registration database is confidential and not open to public view. This proposal requires accuracy and adequacy but offers the submitter no way to verify the information furnished by third parties exists or matches prior data furnished for registration. The only way accuracy, of all data elements, will be determined is by refusal at the time of arrival. The only remedy after arrival and refusal would be to somehow ascertain the problem field, obtain the correct information, remove the original prior notice, and retransmit the data. The cargo would have to be held at the port of arrival under secured storage, adding to congestion of our ports and excessive costs to the importer. It would add additional workload to the electronic system and FDA resources. Validation is now provided under both Customs ABI system and FDA OASIS processing for admissibility data. The proposal must be amended to provide electronic validation at the time prior notice is made and some means to verify registration numbers.

Proposal suggests the average entry contains 2.6 line items and would require one hour to preparation and transmission.

The FDA analysis of the total line items processed and labor time required is flawed. FDA is basing its analysis on 2001 data, which did not require complete transmission of grower or individual line breakout for different seafood sizes. Only produce shipper information is now required. Grower information is being furnished under hard copy as requested by FDA. Following is a comparison between 2001 and proposal line item:

Produce shipment containing 2 types of produce, from one shipper, with each type from five different growers:

Present line item requirement:
2 types with same shipper = 2 OASIS line items and one OASIS transmission

Under this proposal:
2 types from 5 different growers = 10 OASIS line
Items (three growers per notice transmission) with 4 prior notice transmissions.

> The number of required line items for the same shipment increased by five-fold. This 2001 average produce shipment (FDA 2.6 lines per entry) would not take the estimated 1-hour to compile the data etc. but would take 3.8 hours (23 min. per line x 10 lines) under this proposal.

The same would be true for a seafood shipment, which now does not now require line items for size or can codes.

Bottom line is that the costs involved in complying with this proposal are inaccurate as they are based on a different 2001 data requirement base. It is estimated the cost to comply with this proposal would add 50%-60% to the basic entry costs. I would suggest a more accurate determination be made based on standard approved statistical sampling of current data and the increased estimated line items which will be required under this proposal.

Proposal suggests the data transmission requirement could be accomplished with a basic computer and ISP connection.

FDA is inaccurate in its assumption that vast amounts of data can efficiently be transmitted through the Internet using a basic computer and a $20.00/month ISP service. U.S. Customs has many years of experience in the transmission of data required by this proposal. Even using ISDN high-speed technologies they are not always able to meet the data flow during peek times of the working day. The true cost of high-speed data transmission and its associated programming, equipment, and training must also be factored in. In reality this would add an inordinate amount of cost to develop a new data processing system or alter the present systems established by Customs. It would be unreasonable or may not be able to be accomplished this by the December 2003 deadline.

Proposal requires notification of actual arrival time of cargo no less than one hour or more than 3 hours of actual arrival.

The estimated labor cost for complying with this proposal is based on a normal 8 hour, five day work week, but the provision for notification of exact arrive date and arrival time within a 4 hour window would require some type of 24/7/365 operation. The extra labor overtime have not been factored into the estimated compliance cost. Each submitter would be required to each prior notice transmission for one identical piece of information. Each arriving conveyance could have hundreds if not thousands of prior notice updates. The exact time of arrival is very hard to accurately obtain and would lead to vast amounts of conflicting information and possible refusals or unwarranted FDA action. U.S Customs is responsible for arriving all cargo into the United States.

A simple solution would be to have U.S. Customs notify FDA of arrival time upon notified to them by the carrier. This would require one data transmission and more accurately allow FDA Inspectors to meet the cargo in conjunction with Customs. If enacted as proposed these requirements would drive many small importers and brokers from the importation of food products thus denying the American consumer access to a safe and reasonable food supply.

Submitter must indicate intention to amend and can only be amended once for very specific items.

This provision does not allow for amendments to the intermodal information. In the air environment actual port of arrival information may change due to weather or aircraft availability. Many times cargo will be transshipped at a U.S. airport or it would be necessary to land for weather or fuel considerations. The provision does allow for amendment of this type of information and again would require a 24/7/365 operation. No provision is provided for clerical errors other than removal and complete retransmission. This would burden the systems and may prevent information reaching the agency in timely manor.

Support Of Additional Comments Being Submitted By Other Trade Organizations

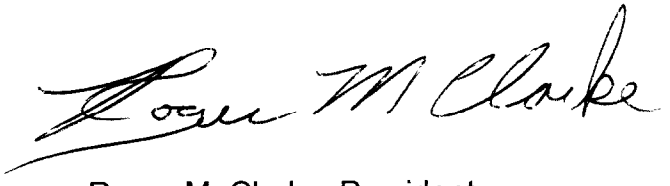
We are a member of the National Customs Brokers & Forwarders Association of America, Inc., the Los Angeles Customs Brokers and Freight Forwarders Association, and the National Fisheries Institute, who are also presenting additional comments on this proposal. We have worked with the National Coalition of Food Importing Associations in collating information from various importing entities and analyzing these proposals as presented. The major adverse effects to the orderly flow of international trade and inordinate high cost to the importing community, and in turn the consumer of the United States are contained in their comments. As an active member of these organizations we have aggressively reviewed this proposal we strongly support the additional comments be presented by all of these organizations.

I would like to thank the agency for this opportunity to express our many concerns on this proposal as written. Our comments are presented in the spirit of cooperation and understanding of the mandates of the Act. We have attempted to offer some reasonable alternatives, which could be supported by the importing community. I hope by the many various comments being presented to the FDA you will realize the real world consequences of proceeding with this proposal without reasonable adjustments.

If I can furnish any assistance, additional information, or answer any questions you may have, please do not hesitate to contact me.

Sincerely,

Williams Clarke Company, Inc.



Roger M. Clarke, President